

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the circular groove must be shown or the feature(s) canceled from the claim(s). Please note that while the Examiner acknowledges that a groove can be said to be illustrated, the view presented in the drawings was only a side view and thus it cannot be said that the groove was circular or even that it extended about the entire top surface. It is possible that it was illustrating two separate grooves. Therefore, the Examiner would like reference as to what drawing illustrates this. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21,23-27,29,30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new limitation in claim 21, that the groove is “circular” was not found in the written disclosure and is new matter. The Applicant refers the Examiner to paragraphs 109,110 but these paragraphs do not even mention there is a groove in the surface. Additionally, it is also interesting that the paragraph mentioned says the mesh is oval, which is not an exact circle. A circle is a broader version of the term oval and Applicant fails to disclose this. However, also noteworthy to mention is that while the drawing (only in side view) show a groove, it does not show a top view that the groove extends around the entire surface. Thus it is plausible that the mesh may have only a section that extends down into the groove.

Therefore, since the specification never mentioned the plates have a circular groove, let alone have a groove, it is new matter.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the written disclosure failed to describe the plates having “exterior surfaces with a circular groove disposed therein” and also that the “vertebral body contact element has a convex central portion and a downwardly bent perimeter, such that the perimeter corresponds to the circular groove of the exterior surfaces”.

The abstract of the disclosure is objected to because it should describe the claimed invention as it was noted that an amendment to the abstract was submitted (4/10/06) which does not describe the claimed invention and is thus not entered. Correction is required or the original abstract will remain. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

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351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21,23-27,29,30 are rejected under 35 U.S.C. 102(e) as being anticipated by both Errico et al. 6723127, 7122055.

The applied references have a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the references, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the references was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 21,23,24,26-30,41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner (5370697) in view of Krebs et al. (5926685) and Hedman et al. (4759769) and Trieu et al. (2003/195514). Baumgartner shows (Fig. 5) a vertebral contact element **44** on the exterior surfaces having a resting shape of a dome convexly extending from an orthopedic device **2** such that a gap is formed between the central portion of the contact element or mesh and the exterior surface of the baseplate. Baumgartner discloses the contact element is a wire mesh (col. 3, lines 54-57) that is porous. The mesh is fully capable of having a convexity depth or footprint approximating the depth of a concave surface in a vertebrae. However, Baumgartner fails to disclose

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the outer surface having a groove or an osteoconductive feature, such as a coating for attaching the exterior contact element. Krebs et al. teach (Fig. 8A) that a groove is disposed in an implant surface to secure a mesh **40** using a coating. Krebs also teaches that the perimeter or contact surface of the mesh, along with the groove in the implant surface are coated to attach the two elements together, col. 6, lines 40-46, 52-56. Krebs et al. teach that a coating or binder is used to secure a metal mesh to the surface of the implant, col. 2, lines 14, 17, 36-39. It would have been obvious to one of ordinary skill in the art to incorporate a groove in the exterior surface to retain the perimeter or surface of the mesh that contacts the implant surface therein as taught by Krebs et al. and utilize a coating or binder held in a groove also taught by Krebs et al. with the implant of Baumgartner such that exterior surface modifications secure the mesh to the implant stronger and eliminates any detachment of the mesh from the baseplates. Additionally, Baumgartner and Krebs fail to disclose explicitly a circular groove or a bent downward perimeter corresponding to the circular groove. Trieu et al. teach (Fig. 14) that a perimeter is bent downward to correspond to a groove a prosthetic repair device. Hedman et al. teach a circular groove (52) to correspond to a spring structure. It would have been obvious to one of ordinary skill in the art to modify the groove to accommodate the mesh structure to be circular as taught by Hedman et al. and to have the mesh perimeter bent downward as taught by Trieu et al. with the prosthetic spinal device of Baumgartner as modified with Krebs et al. such that it is effectively retained in the groove and the stress to deflect under a load is prevented by bending downward to correspond to the groove. To form a circular groove only involves routine skill in the art

and a change in shape of the groove would not materially affect the structural function of the mesh.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner '697 in view of Krebs et al. '685 and Hedman et al. '769 and Trieu et al. '514 as applied to claim 21 above, and further in view of Koch et al. (4969907). Baumgartner in view of Krebs et al. is explained above. However, Baumgartner as modified by Krebs et al. fail to disclose the coating is a plasma spray. Koch et al. teach an implant **1** body's exterior surface has a coating **5** to secure a contact element **6**. Koch also teaches that the coating secures the implant to the contact element and can be a plasma spray, col. 2, lines 3-6,44-48. It would have been obvious to one of ordinary skill in the art to alternatively use a plasma spray coating to retain a mesh to an implant surface as taught by Koch et al. with the mesh secured to the implant of Baumgartner as modified by Krebs et al. and Hedman et al. and Trieu et al. such that it allows the coating to be applied to the baseplates at the desired location.

Response to Arguments

Applicant's arguments with respect to claim 21 have been considered but are moot in view of the new ground(s) of rejection. The Applicants argue that Baumgartner fail to disclose a gap and an initial resting shape of a dome with a central convex central portion with a perimeter having a bent downward portion to correspond to the groove. First it should be noted that despite Applicant's argument that Baumgartner may include additional structure, some element between the mesh and plate (not mentioned in

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Baumgartner) not required by Applicant's invention, that Baumgartner still discloses the invention as claimed. The fact that it MAY disclose additional structure not claimed is irrelevant to the issue of patentability. Clearly, there is a gap between the mesh and plate regardless of whether some element is disposed in the space or not. Applicants also argue that the mesh of Baumgartner is "adapted to the surface of the vertebrae", but fails to appreciate that this is only attaching the structure to the vertebrae and does not eliminate the properties of the flexible mesh from being "deflectable" since it is spaced from the baseplate. Also it is noted that Applicants mention that the Baumgartner reference does not mention the mesh has an "initial" undeflected conformation. The Examiner notes that it can be said that upon implantation or insertion of the prosthetic device of Baumgartner, once positioned against the vertebrae, the mesh has an "initial" undeflected conformation that is convex. There is no recitation in Baumgartner to suggest that the mesh cannot deflect.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700

/Brian E Pellegrino/

Primary Examiner, Art Unit 3738